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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,489	11/09/2001	Janusz B. Pawliszyn	39501	5283

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,489

Applicant(s)

PAWLISZYN, JANUSZ B.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004 and 02 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 4-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of October 24, 2004 ("Amendment") does not render the application allowable.
2. Applicant has voluntarily withdrawn claims 2-15, 17-26, and 29-34. Thus, these claims will not be further treated on their merits.
3. Claim 16 has been labeled as withdrawn (page 4 of Amendment). Although it is not included on the list of withdrawn claims on page 2 of the amendment of August 02, 2004, it will also not be further treated on the merits.
4. Applicant has renumbered claims 27 and 28 as claims 2 and 3, respectively. Thus, there are now two claims labeled claim 2 and two claims labeled claim 3. The examiner will treat "new" claims 2 and 3 as new claims 35 and 36, respectively.
5. Applicant should note that since claims 2-34 have been voluntarily withdrawn from further consideration on the merits, if they are reintroduced in the response to this Office action they may be considered to raise new issues and thus may not be entered.

Status of Objections and Rejections Pending since the Office action of May 03, 2004

6. The objection to claim 1 is withdrawn.
7. The rejection of claim 28 under 35 U.S.C. 112, first paragraph, is withdrawn
8. The rejection of claim 32 under 35 U.S.C. 112, second paragraph, is withdrawn
9. All rejections under 35 U.S.C 102(b) and 35 U.S.C 102(e) are withdrawn. Note that the limitations of claims 2-34 should not be considered allowable since these rejections are withdrawn due to the withdrawal of claims 2-34 (excepting new claims 2 and 3) from further consideration on the merits.
10. All rejections under 35 U.S.C 103(a) are withdrawn. Note that the limitations of claims 2-34 should not be considered allowable since these rejections are withdrawn due to the withdrawal of claims 2-34 (excepting new claims 2 and 3) from further consideration on the merits.

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Claim Objections

11. There are two claims labeled claim 2 and two claims labeled claim 3. The examiner suggest that new claims 2 and 3 be introduced as new claims 35 and 36, respectively.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al. (US 6,176,962 B1) ("Soane") in view of Griffiths (US 6,270,641) ("Griffiths").

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Addressing claim 1, Soane teaches a microchannel for use for separating two or more substances present in a sample (abstract and col. 1, ll. 28-33), the channel comprising a first substrate (14) and a second substrate (12) with a printed component (16) printed on at least one of the substrates in a shape to define a perimeter of the channel (col. 5, ll. 56-64 and col. 6, ll. 30-41), the channel has elongated impermeable side walls ("Thus, the structure may comprise a single enclosed microchannel ..." col. 4; ll. 28-32), the substrates being affixed to one another so that the component is sandwiched between the substrates and is in contact with both substrates (Figure 6 and col. 6, ll. 9-17).

Soane does not mention having the side walls tapered relative to one another.

Griffiths discloses tapering the side walls of an elongated microfluidic channel. See the abstract and Figure 14. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide bends in the elongate channel as taught by Griffiths in the invention of Soane because as taught by Griffiths by folding the channel a much longer effective separation column can be fit within the fixed substrate area. See col. 15, ll. 37-50. It would have been further obvious to one with ordinary skill in the art at the time the invention was made to taper the side walls of the channel as taught by Griffiths in the invention of Soane as modified by Griffiths because as taught by Griffiths this will reduce sample dispersion, thus optimizing the benefit of greater separation with a longer channel length. See col. 15, ln. 51 – col. 16, ln. 8 of Griffiths.

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15. Claims 35 and 36 (new claims 2 and 3) are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al. (US 6,176,962 B1) ("Soane") in view of Griffiths (US 6,270,641) ("Griffiths"), as applied to claim 1 above, and further in view of Ekström et al. (US 5,376,252) ("Ekström").

Addressing claims 35 and 36 (new claims 2 and 3), these claims require means for passing light for whole column imaging detection or said means and transparent substrates. Soane as modified by Griffiths does not mention whole column imaging, although optical detection is disclosed. See col. 11, ll. 1-14 in Soane. Ekström discloses whole column imaging of a microfluidic channel having turns. This is achieved with light passing means (implied since UV detection is disclosed) and transparent plates. See the abstract; Figure 1; and col. 9, ll. 45-59. It would have been obvious to one with ordinary skill in the art at the time the invention was made to perform whole column imaging as taught by Ekström in the invention of Soane as modified by Griffiths because then the separation can be stopped when the sample has been adequately separated rather than waiting for the sample components to traverse the whole length of the channel.

16. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sibbald (GB 2275428 A) in view of Kaltenbach et al. (US 6,033,628) ("Kaltenbach").

Addressing claim 1, Sibbald teaches a microchannel for use for separating two or more substances present in a sample (abstract), the channel comprising a first substrate (2) and a second substrate (1) with a printed component (3) printed on at least one of the substrates in a

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shape to define a perimeter of the channel (abstract and Figures 1-3), the channel has elongated impermeable walls (Figures 1-3) formed by the component, the substrates being affixed to one another so that the component is sandwiched between the substrates and is in contact with both substrates (Figures 1 and 2).

Sibbald does not mention having the sidewalls tapered relative to one another; however, Sibald does disclose having the cross-sectional area of the channel vary along its length (claim 4). Sibald discloses that the cross-sectional area of the channel may be varied to create reservoirs, for example to enhance separation. See page 5, last line bridging to page 6. Kaltenbach discloses a reservoir for separation in a microfluidic channel having tapered walls (Figures 1 and 2; and col. 12:64 – col. 13:18). It would have been obvious to one with ordinary skill in the art at the time the invention was made to taper the inlet and outlet of such reservoirs, such as shown by Kaltenbach, so that the fluid flow will be as little disturbed as possible, that is, to avoid creating turbulence if the reservoirs are to be used for enhanced separation, otherwise the separation so far achieved by travel along the separation channel to the reservoir inlet will be lost and some or all of the separation achieved inside the reservoir will also be lost upon leaving the reservoir if turbulence occurs.

17. Claims 35 and 36 (new claims 2 and 3) are rejected under 35 U.S.C. 103(a) as being unpatentable over Sibbald (GB 2275428 A) in view of Kaltenbach et al. (US 6,033,628) (“Kaltenbach”), as applied to claim 1 above, and further in view of Ekström et al. (US 5,376,252) (“Ekström”).

Addressing claims 35 and 36 (new claims 2 and 3), these claims require means for passing light for whole column imaging detection or said means and transparent substrates. Sibbald does not mention whole column imaging, although detection and transparent substrates are disclosed. See page 3, first full paragraph and the first full sentence on page 6. Ekström discloses whole column imaging of a microfluidic channel having turns (which includes liquid chromatography use, col. 1, ll. 5-11). This is achieved with light passing means (implied since UV detection is disclosed) and transparent plates. See the abstract; Figure 1; and col. 9, ll. 45-59. It would have been obvious to one with ordinary skill in the art at the time the invention was made to perform whole column imaging as taught by Ekström in the invention of Sibbald because then the separation can be stopped when the sample has been adequately separated rather than waiting for the sample components to traverse the whole length of the channel.

18. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sibbald (GB 2275428 A) in view of Griffiths (US 6,270,641) ("Griffiths").

Addressing claim 1, Sibbald teaches a microchannel for use for separating two or more substances present in a sample (abstract), the channel comprising a first substrate (2) and a second substrate (1) with a printed component (3) printed on at least one of the substrates in a shape to define a perimeter of the channel (abstract and Figures 1-3), the channel has elongated impermeable walls (Figures 1-3) formed by the component, the substrates being affixed to one

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another so that the component is sandwiched between the substrates and is in contact with both substrates (Figures 1 and 2).

Sibbald does not mention having the sidewalls tapered relative to one another; however, Sibbald does disclose having the cross-sectional area of the channel vary along its length (claim 4). Sibbald also discloses a folded elongated microfluidic channel. See Figure 3.

Griffiths discloses tapering the sidewalls of a folded elongated microfluidic channel. See the abstract and Figure 14. It would have been further obvious to one with ordinary skill in the art at the time the invention was made to taper the side walls of the folded channel as taught by Griffiths in the invention of Sibbald because as taught by Griffiths this will reduce sample dispersion, thus optimizing the benefit of greater separation with a longer channel length. See col. 15, ln. 51 – col. 16, ln. 8 of Griffiths.

19. Claims 35 and 36 (new claims 2 and 3) are rejected under 35 U.S.C. 103(a) as being unpatentable over Sibbald (GB 2275428 A) in view of Griffiths (US 6,270,641) (“Griffiths”) as applied to claim 1 above, and further in view of Ekström et al. (US 5,376,252) (“Ekström”).

Addressing claims 35 and 36 (new claims 2 and 3), these claims require means for passing light for whole column imaging detection or said means and transparent substrates. Sibbald as modified by Griffiths does not mention whole column imaging, although detection and transparent substrates are disclosed. See page 3, first full paragraph and the first full sentence on page 6. Ekström discloses whole column imaging of a microfluidic channel having

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Final Rejection

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
January 5, 2005